Pharmacy Compounding Advisory Committee

October 14, 15, and 16, 1998
Advisory Committee Conference Room, 1066
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

AGENDA

Objectives:

1. Introduce certain issues associated with implementation of Section 127 of the FDA Modernization Act on Pharmacy Compounding

2. Review bulk drug substances nominated for inclusion on a list of bulk drug substances that may be used in compounding that qualifies for the applicable statutory exemptions that are neither components of FDA approved products nor covered by a United States Pharmacopeia/ National Formulary monograph.

3. Review drug products proposed for inclusion on a list of products that have been withdrawn or removed from the market for reasons of safety or effectiveness that may not be used in compounding that qualify for the applicable statutory exemptions.

Day 1: Wednesday, October 14, 1998

8:30 a.m. ***Call to Order/General Introductory Remarks*** *Dr. Juhl*

Conflict of Interest *Ms. Topper*

9:00 a.m. **Presentations from Invited Speakers**

Kate Lambrew Hull, Legislative Assistant to
Senator Tim Hutchinson

John A. Gans, Pharm. D., Executive Vice President, American Pharmaceutical Association

Bruce Roberts, R.Ph., FIACP, International Academy of Compounding Pharmacists

	John D. Siegfried, M.D., Senior Medical Advisor, Pharmaceutical Research and Manufacturers of America	
	Debra Brownstein, Director of Marketing, Dey Laboratories, Generic Pharmaceutical Industry	
	Larry D. Sasich, Pharm. D., M.P.H., FASHP, Public Citizen Health Research Group	
10:00 a.m.	***Break***	
10:10 a.m.	Introductory Remarks	*Dr. Woodcock*
10:15 a.m.	FDA Overview of Pharmacy Compounding Legislation	*Ms. Axelrad*
10:30 a.m.	Criteria for Selection of Bulk Drug Substances for List	*Captain Tonelli*
12:00 p.m.	***Lunch***	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Introduction of Bulk Drug Nominations	*Captain Tonelli*
2:10 p.m.	Presentation and Discussion of Bulk Drug Nominations, Groups 1-4	
	FDA Presentation of Each Group	*Captain Tonelli*
	Presentations from Nominators	*Ms. Ford, IACP*
3:00 p.m.	***Break***	
3:10 p.m.	Discussion of Bulk Drug Nominations Continued	
5:00 p.m.	***Adjourn***	

Day 2: Thursday, October 15, 1998

8:30 a.m.	***Call to Order***	
8:40 a.m.	Discussion of Bulk Drug Nominations Continued	
10:00 a.m.	***Break***	
10:15 a.m.	Discussion of Bulk Drug Nominations Continued	
12:00 p.m.	***Lunch***	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Introduction to Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness	*Captain Scott*
3:00 p.m.	***Break***	
3:10 p.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness	
5:00 p.m.	***Adjourn***	

Day 3: Friday, October 16, 1998 (If necessary)

8:30 a.m.	***Call to order***	
8:40 a.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness Continued	
10:00 a.m.	***Break***	
10:10 a.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons	

	of Safety or Effectiveness Continued
12:00 p.m.	***Lunch***
1:00 p.m.	Open Public Hearing
2:00 p.m.	Discussion of Proposed List of Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness Continued
3:30 p.m.	Closing Remarks and Adjourn